



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



9 MAY 2017

MEMORANDUM FOR SGVT

ATTN: CAPT DONOVAN REED

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Retrospective Analysis of the Post-Operative Changes in Higher Order Aberrations: A Comparison of the EX500 to the Allegretto and VISX S4 Laser in Refractive Surgery** presented at/published to **Journal of Military Medicine and San Antonio Military Health Systems and Universities Research Forum, 16 June 17** in accordance with MDWI 41-108, has been approved and assigned local file #**17229**.
2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

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PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1 TO CLINICAL RESEARCH 2 FROM (Author's Name, Rank, Grade, Office Symbol)
Donovan Reed, Capt, O-3, 959 C/SPS

3 GME/CHSE STUDENT
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4 PROTOCOL NUMBER
20150093H

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Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the Ex500 to the Allegretto and Visx lasers.

6 TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED

Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the Ex500 to the Allegretto and Visx lasers.

7 FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE

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Apsey, Doug. A., douglas.apsy.2.ctr@us.af.mil

15 DUTY PHONE/PAGER NUMBER

210-292-2554

16 AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (if not 59 MDW)
a. Primary/Corresponding Author Reed, Donovan S.	O-3/Capt	CSPS 959	
b. Apsey, Douglas A.	O-6/Col (Ret)	59 TRS	
c. Steigleman, Walter A.	O-5/CDR	59 TRS	
d. Townley, James R.	O-5/Lt Col	59 TRS	
e. Caldwell, Michael C.	O-5/Lt Col	59 TRS	

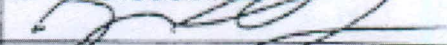
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18 AUTHOR'S PRINTED NAME, RANK, GRADE

Donovan Reed, Capt, O-3

19 AUTHOR'S SIGNATURE



20 DATE

04 Apr 2017

21 APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE

Brett Davies, Maj, APD

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11 Apr 2017

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Rocky Calcote, PhD, Clinical Research Administrator

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Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs

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Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the WaveLight® EX500 to the VISX® S4 laser in refractive surgery

Donovan Reed MD, Doug Apsey OD,
Walter Steigleman MD, Matthew Caldwell MD,
J. Richard Townley MD

Wilford Hall Ambulatory Surgical Center (WHASC)

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Introduction

- PRK & LASIK reduce spherical and cylindrical defocus
 - Aberrations of the cornea are insufficient to characterize the entire visual quality of an eye.
- Measurement of the entirety of ocular aberrations is the most definitive means to establish the true effect of refractive surgery on image quality and visual performance.¹
- PRK and LASIK increase wavefront aberrations and alter the comparative contributions of coma- and spherical-like higher order aberrations often inherent to the natural eye.²
- RMS wavefront error as a metric of global image quality³
- Moshirfar et al. demonstrated both the VISX® CustomVue and WaveLight® Allegretto systems perform equally in terms of visual acuity, safety, and predictability in both PRK and LASIK^{4,5}
 - Higher-order and spherical aberrations during photorefractive keratectomy, not statistically significant⁴

Purpose

- Future advancements in refractive surgery
- Investigate the utility of the current excimer lasers employed by the DoD in terms of induced aberrations to maximize refractive treatment.
- The impact on post-operative higher order aberrations between the currently available DoD laser platforms
 - Offer insight as to which provides the best overall image quality following refractive surgery in the active duty and DoD beneficiary population

Methods

- Retrospective analysis
- Pre and post-operative changes in higher order aberrations following refractive surgery with the WaveLight® EX500 Excimer Laser System (Alcon, Fort Worth, TX) and the VISX® Star S4 IR Excimer Laser System (Abbott Medical Optics, Santa Ana, CA)
- RMS
 - Pentacam

Inclusion Criteria

- Active duty military or DoD beneficiaries who had refractive surgery at the Joint Warfighter Refractive Surgery Center and:
 - were 21 years of age or older
 - had PRK or LASIK refractive surgery
 - completed a 3 month follow-up visit

Exclusion Criteria

- Subjects who do not meet the inclusion criteria listed
- Subjects who previously had refractive surgery
- Patients who did not have follow-up data
- Pregnant women or incompetent adults

Methods

- Matching
- SPSS statistics
 - Student's T-test
 - Regression analysis: preoperative SE
 - Larger refractive errors = larger ablations

Results

	PRK	LASIK
VISX		
Age at Surgery (Mean)	29.4	31.5
Gender (Total)	74M 26F	16M 6F
PreOp MSE	-3.33	-2.73
Total Eyes	100	22
EX500		
Age at Surgery (Mean)	29.1	30.2
Gender	56M 40F	16M 6F
PreOp MSE	-3.35	-4.38
Total Eyes	96	22

Table 1: Patient Demographics

Results

	Mean Δ RMS	SD	p-Value (T-test)
PRK			0.431
VISX [®]	0.00122	0.02583	
EX500	0.004323	0.02916	
LASIK			0.295
VISX	0.00841	0.03011	
EX500	0.0174	0.02417	

Table 2: Change in RMS statistics

Results

	PRK		LASIK	
	b	p	b	p
PreOp MSE	-0.001	0.551	-0.003	0.161
Laser (EX500 w VISX)	0.003	0.433	0.004	0.670

Table 3: Regression Analysis concerning pre-operative refractive error for both LASIK and PRK

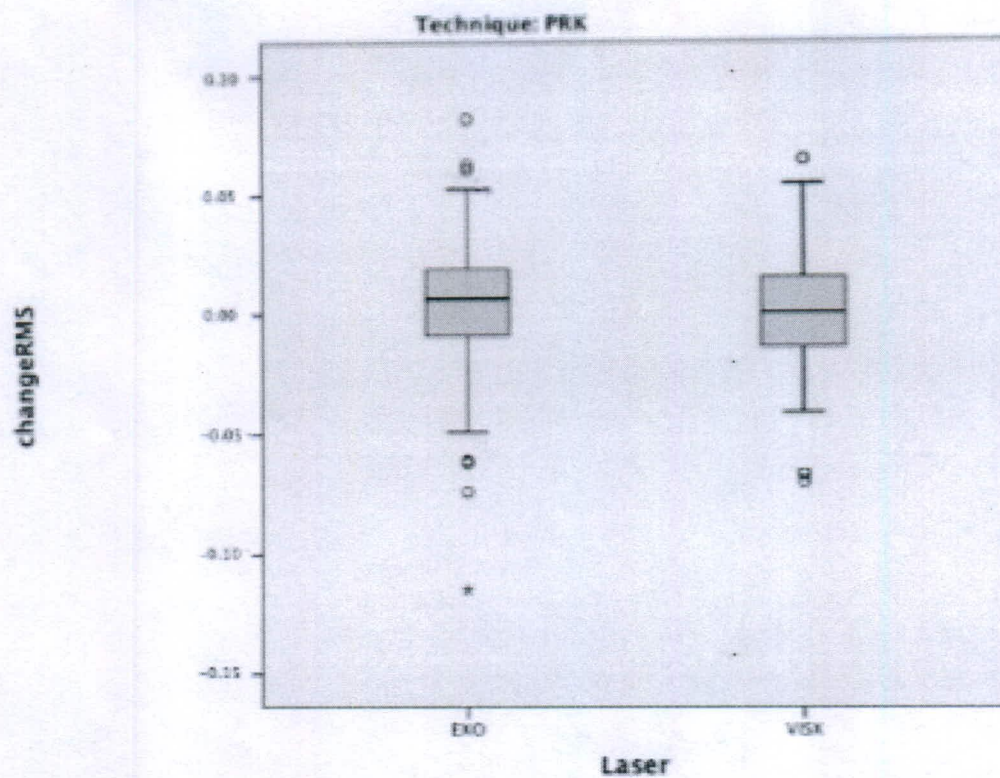


Figure 1: Change in RMS data for PRK between the VISX® and WaveLight® EX500 Lasers. p-value is 0.431

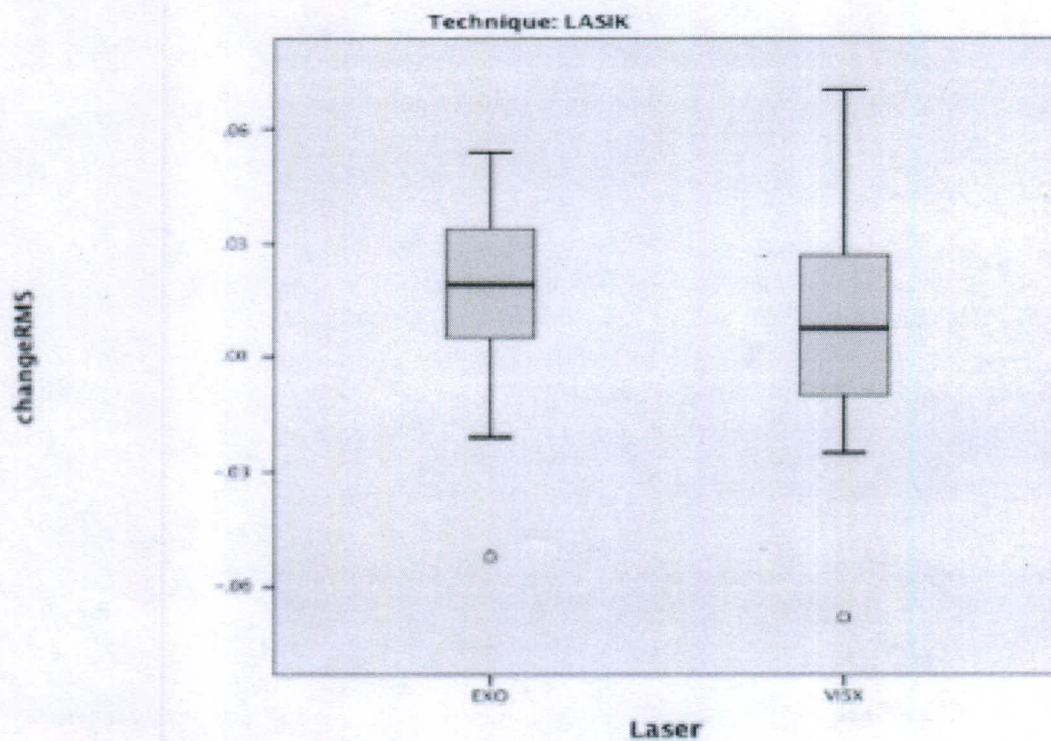


Figure 2: Change in RMS data for PRK between the VISX® and WaveLight® EX500 Lasers. p-value is 0.295

Discussion

- No statistically significant difference
 - Adjusting for preoperative refractive error
- Observations:
 - LASIK higher pre-operative MSE in EX500
 - VISX laser lower induced RMS values
 - 2-4x higher in each category for EX500
 - Moshirfar et al.
- Power

Limitations

- Design
- Sample size
- Generalizability
- Clinical significance

Recommendations

- Further investigation of visual outcomes
- Additional factors
 - Cost
 - Patient characteristics
 - Surgeon preference

References

1. Moren-Barrisuo E, Lloves JM, Marcos S, Navarro R, Llorente L, Barbero S. Ocular aberrations before and after Myopic Corneal Refractive Surgery: LASIK-Induced Changes Measured with Laser Ray Tracing. *Invest Ophthalmol Vis Sci*. 2001 May;42(6):1396-403.
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3. Thibos LN, Applegate RA, Schwiegerling JT, Webb RH. Members VST Standards for reporting the optical aberrations of eyes. *Vision Science and its Applications TOPS Volume*. 2000;35.
4. Moshirfar M, Betts BS, Churgin DS, Hsu M, Neuffer M, Sikder S, Church D, Mifflin MD. Prospective, randomized, fellow eye comparison of WaveLight Allegretto Wave Eye-Q versus VISX® CustomVue TM STAR S4 IRTM in photorefractive keratectomy: analysis of visual outcomes and higher-order aberrations. *Clin Ophthalmol*. 2011;5:1185- 93.
5. Moshirfar M, Betts BS, Churgin DS, Hsu M, Neuffer M, Sikder S, Church D, Mifflin MD. A prospective, randomized, fellow eye comparison of WaveLight Allegretto Wave Eye-Q versus VISX® CustomVue TM STAR S4 IRTM in laser in situ keratomileusis (LASIK): analysis of visual outcomes and higher-order aberrations. *Clin Ophthalmol*. 2011;5:1339-47.



Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the WaveLight® EX500 to the VISX® S4 laser in refractive surgery

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Introduction

Both photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) effectively reduce spherical and cylindrical defocus, the key lower order optical aberrations contributing to decreased visual acuity. Aberrations of the cornea are insufficient to characterize the entire visual quality of an eye. Measurement of the entirety of ocular aberrations is the most definitive means to establish the true effect of refractive surgery on image quality and visual performance.¹

Both PRK and LASIK have been demonstrated to increase wavefront aberrations of the cornea and alter the comparative contributions of coma- and spherical-like higher order aberrations often inherent to the natural eye.² Previous studies have utilized the root-mean-square (RMS) wavefront error as a metric of global image quality, thus effectively isolating different aberration orders contributing to post-operative vision.³ Mosierfar et al. demonstrated both the VISX® CustomVue and WaveLight® Allegretto systems perform equally in terms of visual acuity, safety, and predictability in both PRK and LASIK refractive surgery procedures.^{4,5} Both platforms induced a comparable degree of higher-order and spherical aberrations during photorefractive keratectomy, though no statistically significant difference in terms of the RMS of higher-order optical aberrations was demonstrated.⁶

As future advancements in refractive surgery are being directed toward customized ablations to correct not only lower-order aberrations, but also higher-order aberrations specific to the individual eye, it is important to investigate the utility of the current excimer lasers employed by the DoD in terms of induced aberrations to maximize refractive treatment. The impact on post-operative higher order aberrations between the currently available DoD laser platforms was investigated to offer insight as to which provides the best overall image quality following refractive surgery in the active duty and DoD beneficiary population.

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Methods

A retrospective analysis was performed to evaluate the pre and post-operative changes in higher order aberrations following refractive surgery with the WaveLight® EX500 Excimer Laser System (Alcon, Fort Worth, TX) and the VISX® Star S4 IR Excimer Laser System (Abbott Medical Optics, Santa Ana, CA) by evaluating the RMS value of the higher order corneal aberrations post-operatively.

Inclusion Criteria:

- Active duty military or DoD beneficiaries who had refractive surgery at the Joint Warfighter Refractive Surgery Center and;
 - were 21 years of age or older
 - had PRK or LASIK refractive surgery
 - completed a 3 month follow-up visit

Exclusion Criteria:

- Subjects who do not meet the inclusion criteria listed
- Subjects who previously had refractive surgery
- Patients who did not have follow-up data
- Pregnant women, or incompetent adults

Patient demographics were matched to avoid bias. Utilizing SPSS statistics software, the mean change in RMS values between the two lasers and refractive surgery procedures were determined. A student's t-test was performed to compare the root mean square of the higher order aberrations of the subjects' corneas from the lasers being studied. A regression analysis was performed to adjust for preoperative SE, as larger refractive errors often require larger ablations, which could ultimately affect the amount of higher order aberrations post-operatively.

Results

	PRK	LASIK
VISX		
Age at Surgery	26.4	31.5
Gender	14M/10F	18M/10F
PreOp SE	-1.33	-2.71
Total eyes	50	28
EX500		
Age at Surgery	26.1	30.2
Gender	10M/10F	13M/15F
PreOp SE	-1.33	-4.34
Total eyes	40	28

Table 1. Patient demographics

	Mean RMS	SD	P-value (T-test)
PRK			
VISX®	0.00222	0.00260	
EX500	0.00033	0.00115	
LASIK			0.195
VISX®	0.00641	0.00171	
EX500	0.01174	0.00417	

Table 2. Change in RMS statistics

	PRK		LASIK	
	S	P	S	P
PreOp SE	-0.001	0.551	-0.003	0.161
Laser (EX500)	0.000	0.403	0.004	0.610

Table 3. Regression analysis concerning pre-operative refractive error for both LASIK and PRK

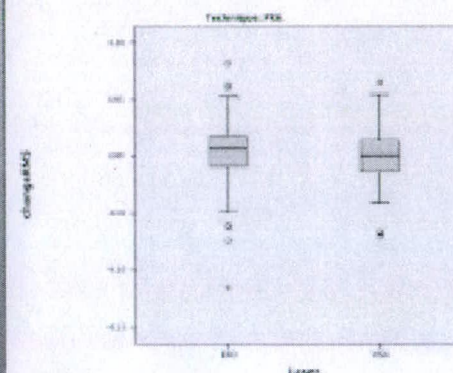


Figure 1: Change in RMS data for PRK between the VISX® and WaveLight® EX500 lasers. P-value is 0.431.

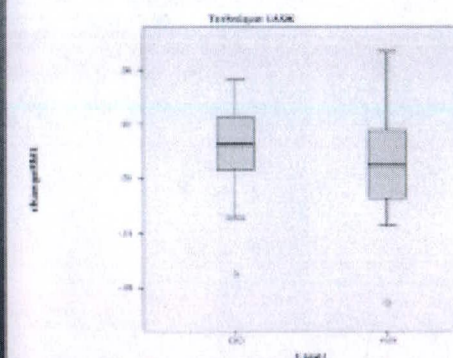


Figure 2: Change in RMS data for LASIK between the VISX® and WaveLight® EX500 lasers. P-value is 0.269.

Discussion

The results suggest no statistically significant difference concerning induced higher order aberrations between the two laser platforms for either LASIK or PRK. After adjusting for preoperative refractive error there was still no statistically significant difference. This is despite the fact patients who received LASIK did have a significantly higher pre-operative SE in the EX500 group. It is likely the statistical significance of this study was hindered by the power, given the relatively small sample size. For instance, every value calculated demonstrated the VISX laser to have lower induced RMS values. Additionally, the induced higher order aberrations by the EX500 were two to four times higher in each category. These findings coincide with the study performed by Mosierfar et al.^{4,5} Additional limitations of the study include its design and the generalisability of the study, as the Department of Defense population may be significantly different from the typical refractive surgery population in terms of overall health and preoperative refractive error.

The level at which induced higher order aberrations reach clinical significance is debatable and it is difficult to quantify subjective reports of visual disturbances. Therefore, it remains a challenge to determine whether statistically significant differences in higher order aberrations have a clinically significant impact on visual outcomes. Further investigation of visual outcomes between the two laser platforms should be investigated before determining superiority in terms of visual image and quality post-operatively. Additional factors such as cost, availability, patient characteristics, and surgeon preference should be taken into consideration determining the most appropriate laser to utilize for refractive surgery.

References

1. Mosierfar B, Reed D, Apsey D, Steigleman W, Caldwell M, Townley J. Corneal aberrations before and after topography-guided refractive surgery: LASIK-induced changes compared with laser ray tracing. *Invest Ophthalmol Vis Sci*. 2001;42(12):3564-3571.
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4. Mosierfar B, Reed D, Apsey D, Steigleman W, Caldwell M, Townley J. Corneal topography: Corneal aberrations and visual quality. *Optom*. 1999;80(12):12-17.
5. Mosierfar B, Reed D, Apsey D, Steigleman W, Caldwell M, Townley J. Corneal topography: Corneal aberrations and visual quality. *Optom*. 1999;80(12):12-17.